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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/813,214
Filing Date: March 29, 2004
Appellant(s): MOGENSEN ET AL.

Heidi Dare
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 6 August 2009 appealing from the Office action mailed 22 April 2009.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/687,568: an appeal brief was filed 5 August 2009

11/031,635: an appeal docketing notice was mailed 7/30/09

**(3) Status of Claims**

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 50, 52, 53, 56, 58, 66, 67, 69, 72, 78, 79, 82-88, and 90-92.

Claims 60-64 and 93-100 are allowed.

Claims 51, 54, 55, 57, 59, 65, 68, 73-77, 80, 81, and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

**WITHDRAWN REJECTIONS**

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The rejections of claims 51, 54, 55, 57, 59, 65, 68, 80, 81, 87, 89 and 93-100 are withdrawn. The status of these claims in detailed in (3) above.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 4,894,054 | MISKINYAR | 1-1990 |
| 6,293,925 | SAFABASH | 9-2001 |
| 5,807,316 | TEEPLE | 9-1998 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 50, 56, 67, 69-72, 78, 82-88, 90-92 and are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 5,527,287).

Miskinyar teaches a sterile insertion set with housing (74) and cannula (22); a plunger (18); a lock (56); a spring (70);

a forward end (62), a cover (72) covering an opening (60). As to claim 82-85, engagement areas on button (33); claim 86-88, back cover (38).

2. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar as applied to claims above, and further in view of Teeple, Jr (US 5,807,316).

Miskinyar does not teach indicia relating to the shelf life of the device on the cover. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient.

3. Claims 52, 53, 66, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash as applied above, and further in view of Miskinyar.

Miskinyar teaches a subcutaneous injector which is sterile and provided with front (72) and back (38) covers.

Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500), a repositionable cover (414), a plunger (504), a spring drive (507), lock (552), and manually deformable housing/trigger (508) to release the plunger. See Figs 35-40g. Claim 52: See adhesive (406). Claim 53, 79: See glucose sensor Col 1 line 31.

It is well known in the medical arts to provide sterile devices, especially when the devices pierce the skin, in order to prevent infection and the spread of disease. Miskinyar teaches a similarly shaped (flatten round disc) device which similar plunger (spring powered, button actuated) which may be sterilized and has front and back covers. The front cover of Miskinyar is a thin membrane, similar to the adhesive cover of Safabash. The rear cover prevents unwanted discharge of the plunger.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the front and back covers of Miskinyar with the device of Safabash to provide a sterile insertion set, in order to prevent infection and the spread of disease.

**(10) Response to Argument**

**A. 102 REJECTIONS**

**1. Miskinyar**

**a. Claims 50, 56, 67 and 69-70**

Appellant argues that the insertion set is not separable from the plunger as required by claim 50. The term "removabaly" is a capability term and the needle is capable of being removed by cutting, snapping, breaking, etc. In a device claim, the device must only be capable of, not intended or disclosed as, performing the claimed function. Furthermore, there is nothing in the claims about the needle or cannula remaining in the patient or even being removable once inside the patient.

There is no plain meaning of the term "infusion set" which limits an infusion set to a device removable from an "injector device" (which is also not given a special definition). An infusion set may also be a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery. Appellant argues that by stating in the specification that an infusion set "generally includes..." they have limited the meaning of the term. It is the examiner's position that "infusion set" has not been limited by the specification and one of ordinary skill in the art would consider a cannula and ampoule an infusion set.

**b. Claim 71**

Appellant argues that sterile tape 72 is not flow-through sterilizable. See Col 8 lines 50-60 teaches that the device is assembled in a sterile room and that the sterile tape is applied in the room. The tape allows for the sterile air to pass through into the open area below the ampoule, see Fig 2. This meets the capability limitation of claim 71 of "allowing through-flow" of a sterilizing agent (i.e. sterile air) into said device housing.

**c. Claims 72, 78, 86 and 87**

(see discussion in a above for insertion set/separable arguments). Appellants argue Miskinyar does not teach a manually deformable housing. The button 33 is a part of the housing, generally housing 10. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should no be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would

be. The button moves up and down, which makes it manually deformable from a first (up) to a second (down) position, relative to the housing. Thus, the housing (as a whole) changes shape or deforms. The button may be pushed at the sides to deploy the plunger.

**d-g. Claim 82-Claim 85**

The sides of the button or top of the button, in fact any surface of the button, is a manual engagement area. The button may also be pushed at both sides to deploy the plunger.

**h. Claim 88**

Appellant argues that sterile tape 72 is not flow-through sterilizable. See Col 8 lines 50-60 teaches that the device is assembled in a sterile room and that the sterile tape is applied in the room. The tape allows for the sterile air to pass through into the open area below the ampoule, see Fig 2. This meets the capability limitation of "allowing through-flow" of a sterilizing agent (i.e. sterile air) into said device housing.

**i. Claims 90-92**

Appellant argues that sterile tape 72 is not flow-through sterilizable. See Col 8 lines 50-60 teaches that the device is assembled in a sterile room and that the sterile tape is applied in the room. The tape allows for the sterile air to pass through into the open area below the ampoule, see Fig 2. This meets the limitation of "allowing through-flow" of a sterilizing agent (i.e. sterile air) into said device housing.

**B. 35 USC 103**

**1. Miskinyar and Teeple, Jr.**

Applicant argues that the combination of Teeple and Miskinyar would not result in assuring sterile condition of the infusion set. This limitation is taught by Miskinyar alone. The shelf-life in the claims is not limited to the sterile shelf-life of the device. Since the device of Miskinyar includes a drug (in the ampoule) it would be obvious to list the shelf life of that drug on the cover of the device so that an expired or degraded drug is not delivered to the patient.

**2. Safabash et al and Miskinyar**

**a. Claims 52,53,66,78, and 79**

(The rejection of claims 50, 51, 54-57,59,68-70,72,80,81,86,87, and 97-99 is withdrawn)

Applicant did not separately argue the rejection of claims 52, 53, 66, 78 and 79, which are dependent on claims rejected by Miskinyar alone.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ELIZABETH R MOULTON/

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